DATE OUT: 31 Oct 2002

SUBJECT: **EP [x] MP [ ] PRODUCT CHEMISTRY REVIEW**
DP BARCODE No.: D283613
REG./File Symbol No.: 59639-RET
PRODUCT NAME: Chateau Herbicide
COMPANY: Valent USA Corp.

TO: PM #23, Joanne Miller/Daniel Kenny
Herbicide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

Bruce F. Kitchens
31 Oct 2002

BFK
10-31-02

INTRODUCTION:

The registrant, Valent USA Corporation, is submitting an application for the registration of the new end-use product, Chateau Herbicide. The active ingredient in this product is Flumioxazin Technical (97.9%) at a label nominal concentration of 41.5% a.i. and is intended for use as an herbicide. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 30 Nov 2002, a draft label, and product chemistry data contained in MRID# 456871-01. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from a registered source of the active ingredient.

2. All inert ingredients are cleared for use in formulated products. In addition, all inert ingredients are exempt from the requirement of a food tolerance.

3. The active ingredient nominal concentration listed on the draft label and the CSF are the same.

4. The draft label contains the appropriate storage and disposal statements.

5. The active ingredient certified limits as proposed on the CSF are acceptable.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formulation CSF, for the proposed end-use product Chateau Herbicide dated 30 Nov 2001 is acceptable.

2. This submission meets the data requirements as specified in 40 CFR 158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation impurities, certified limits, and enforcement analytical method.

3. This submission also satisfies the data requirement as specified in 40 CFR 158.190 with respect to physical and chemical characteristics.

EP [x] MP [ ] PRODUCT CHEMISTRY REVIEW

1. DP BARCODE No.: D283613 2. REG./File Symbol No.: 59639-RET

3. Registration [x] 4. Reregistration [ ], Rereg Case No._____

5. Product Name: Chateau Herbicide

6. Pesticide Type: Fungicide [ ] Herbicide [x]
Insecticide [ ] Rodenticide [ ] Antimicrobial [ ]
Plant Growth Regulator [ ] Others: _____

7. Uses: Food [x] Non food use [ ]

8. Type of Submission: New [x] Resubmission [ ] Amendment [ ]
"ME-TOO" [ ] Alternate Formulation [ ] Repack [ ]
Experimental Use Permit [ ] Other (Specify)_____

9. If "Me-TOO" Registration, this product is [ ] is not [ ]
similar or substantially similar to EPA's Reg. No.:_____,

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.

CONFIDENTIAL STATEMENT OF FORMULA, DATED (30 Nov 2001) :

10. Type of formulation and the sources of active ingredients:

a. Non-integrated formulation system.....[x]

b. Are all technical grade active ingredients used registered? yes [x] no [ ]

c. Integrated formulation system.....[ ]

11. Composition: The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

		% by weight	
Active ingredient(s)	NC	UCL	LCL
Flumioxazin	41.5	42.8	40.2

12. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

yes [x] no [ ]

13. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:

yes [x] no [ ]

14. Clearance of intentionally added ingredients in the formulation for the intended use:

a. Formulation intended for food use under 40CFR§180.1001:

yes [x] no [ ] Some are cleared, others are not [ ]

Cleared under list: c [ ] d [ ] e [ ]

b. Formulation intended for non-food use:

yes [ ] no [x] Some are cleared, others are not [ ]

15. For products produced by an integrated formulation system: All impurities of toxicological significance have an UCL:

yes [ ] no [ ] not applicable [x]

All other impurities 0.1% associated with the active ingredient in the product are reported at their nominal concentrations:

yes [ ] no [ ] not applicable [x]

PRODUCT LABEL, EPA RECEIVED (draft) :

16. The active ingredients statement (chemical identities, nominal concentrations) is consistent with the CSF yes [x] no [ ]

17. The formulation contains one of the following:

10% or more of a petroleum distillate:	yes [ ]	no [x]
1% or more of methyl alcohol:	yes [ ]	no [x]
sodium nitrite at any level:	yes [ ]	no [x]
a toxic List 1 inert at any level:	yes [ ]	no [x]
arsenic in any form:	yes [ ]	no [x]

18. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?

yes [ ] no [ ] not applicable [x]

19. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:

yes [ ] no [ ] not applicable [x]

20. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:

yes [x] no [ ]

PRODUCT CHEMISTRY DATA (GROUP A)

21. Chemical IDs/Manufacture/ Analytical Information	Data Required Fulfilled	MRID No.
830-1550 Product Identity and Composition	Y	456871-01
830-1600 Description of Materials Used to Produce the Product	Y	"
830-1620 Description of Production Process	NR	
830-1650 Description of Formulation Process	Y	456871-01
830-1670 Discussion of Impurities	Y	"
830-1700 Preliminary Analysis	NR	
830-1750 Certified Limits	Y	456871-01
830-1800 Enforcement Analytical Method	Y	"

PRODUCT CHEMISTRY DATA (GROUP B)

24. Physical/Chemical Properties	Data Required Fulfilled	Value or Qualitative Description	MRID No.
830-6302 Color	Y	white	456871-01
830-6303 Physical State	Y	viscous liquid	"
830-6304 Odor	NR		
830-6314 Oxidation/Reduction:Chemical Incompatability	NA	Product did not react with water, monoammonium phosphate, zinc, and potassium permanganate	
830-6315 Flammability/Flame Extension	Y	> 200°C	456871-01
830-6316 Explodability	NA	Product does not contain explosive components	
830-6317 Storage Stability of Product	I	Study in progress	
830-6319 Miscibility	NA	Product not mixed with hydrocarbon solvents	
830-6320 Corrosion Characteristics	I	Study in progress	
830-6321 Dielectric Breakdown Constant	NA	Product not used around electrical equipment	
830-7000 pH	Y	6.7 @ 25°C	456871-01
830-7100 Viscosity	Y	38-84 cP @ 20°C 26-64 cP @ 40°C	"
830-7300 Density	Y	1.15 g/ml @ 20°C	"

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

12/SEPT/2002

MEMORANDUM

Subject:	Name of Pesticide Product:	Chateau Herbicide
	EPA File Symbol:	59639-RET
	DP Barcode:	D283614
	Case No:	072358
	PC Code:	129034
From:	Eugenia McAndrew, Biologist Technical Review Branch Registration Division (7505C)	
To:	Daniel Kenny, PM Team 23 Herbicide Branch Registration Division (7505C)	
Applicant:	Valent U.S.A. Corporation 1333 N. California Blvd., Suite 600 Walnut Creek, CA 94596-8025	

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
129034	Flumioxazin	41.5
	Inert Ingredient(s):	58.5
	Total:	100.0%

ACTION REQUESTED: PM requests review of acute toxicity data for Chateau Herbicide, EPA File Symbol 59639-RET.

BACKGROUND: Valent U.S.A. Corporation has submitted six acute toxicity studies in support of registration of Chateau Herbicide, EPA File Symbol 59639-RET, a new end-use product containing flumioxazin as the active ingredient. The studies were assigned MRID numbers 456871-02 to -07. The studies were conducted at Springborn Laboratories, Inc., Spencerville, Ohio. The product is referred to as "V-53482 4 FL" in the study reports.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for Chateau Herbicide, EPA File Symbol 59639-RET, is as follows:

acute oral toxicity	IV	Acceptable	MRID 45687102
acute dermal toxicity	IV	Acceptable	MRID 45687103
acute inhalation toxicity	IV	Acceptable	MRID 45687104
primary eye irritation	III	Acceptable	MRID 45687105
primary skin irritation	IV	Acceptable	MRID 45687106
dermal sensitization	Negative	Acceptable	MRID 45687107

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #: 059639-00127

PRODUCT NAME: Chateau Herbicide

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear: Long-sleeved shirt and long pants, socks, shoes, and waterproof gloves.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE ORAL TOXICITY TESTING (870.1100 formerly §81-1)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: V-53482 4 FL; 41.5% flumioxazin

CITATION: Rodabaugh, D. (2002) acute oral toxicity in rats with V-53482 4 FL. Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number 3548.28. May 15, 2002. MRID 45687102. Unpublished.

SPONSOR: Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596-8025

EXECUTIVE SUMMARY: In an acute oral toxicity study, five adult, Hsd: Sprague Dawley SD rats/sex (Age: Males: 11 weeks; Females: 8-11 weeks; Weight: 340-357 g males; 193-231 g females; Source: Harlan Sprague Dawley, Inc., Indianapolis, IN) were given a single oral dose of V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid) at 5000 mg/kg. The test substance was administered as received. Body weights were obtained prior to dosing on day 0 and on days 7 and 14. Animals were observed for clinical signs of toxicity and mortality for 14 days post dosing. A gross necropsy examination was performed on all animals at scheduled euthanasia.

Oral LD_{50} Males = > 5000 mg/kg (observed); Oral LD_{50} Females = > 5000 mg/kg (observed)

V-53482 4 FL is classified as Toxicity Category IV based on the observed LD_{50} value in males and females.

All animals survived. Clinical signs included congested breathing in two animals and few feces in one animal. The animals recovered from these symptoms by day 2. No gross abnormalities were noted at necropsy.

This study is classified as Acceptable (870.1100) and satisfies the guideline requirement for an acute oral study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

OBSERVATIONS: All animals survived. Clinical signs included congested breathing in two animals and few feces in one animal. The animals recovered from these symptoms by day 2.

GROSS NECROPSY: No gross abnormalities were noted at necropsy.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: V-53482 4 FL; 41.5% flumioxazin

CITATION: Rodabaugh, D. (2002) acute dermal toxicity in rats with V-53482 4 FL. Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number 3548.29. May 15, 2002. MRID 45687103. Unpublished.

SPONSOR: Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596-8025

EXECUTIVE SUMMARY: In an acute dermal toxicity study, five adult, Hsd: Sprague Dawley SD rats/sex (Age: approximately 11 weeks; Weight: 336-371 g males; 204-216 g females; Source: Harlan Sprague Dawley, Inc., Indianapolis, IN) were dermally exposed to a single application of V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid) at 5000 mg/kg (limit dose) for 24 hours. The test substance was applied to approximately 10% of the total body surface area. Body weights were obtained prior to dosing on day 0 and on days 7 and 14. Animals were observed for dermal irritation, clinical signs of toxicity and mortality daily for 14 days. A gross necropsy examination was performed on all animals at the time of scheduled euthanasia.

Dermal LD_{50} Males = > 5000 mg/kg (observed); Dermal LD_{50} Females = > 5000 mg/kg (observed)

V-53482 4 FL is classified as Toxicity Category IV based on the observed LD_{50} value in both sexes.

All animals survived. One female lost weight during the first week and one female lost weight during the second week. All other animals gained weight. Clinical signs noted were dark material around the nose, eyes and/or mouth, decreased food consumption and decreased defecation. Dermal irritation was observed at all test sites. Necropsy revealed an adrenal nodule and an abscess in the epididymides of one male; no other gross abnormalities were noted.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

OBSERVATIONS: All animals survived. One female lost weight during the first week and one female lost weight during the second week. All other animals gained weight. Clinical signs noted were dark material around the nose, eyes and/or mouth, decreased food consumption and decreased defecation. Dermal irritation was observed at all test sites.

GROSS NECROPSY: Necropsy revealed an adrenal nodule and an abscess in the epididymides of one male; no other gross abnormalities were noted.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE INHALATION TOXICITY TESTING (870.1300 formerly §81-3)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: V-53482 4 FL; 41.5% flumioxazin

CITATION: Rodabaugh, D. (2002) acute nose-only inhalation toxicity in rats with V-53482 4 FL. Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number 3548.30. May 15, 2002. MRID 45687104. Unpublished.

SPONSOR: Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596-8025

EXECUTIVE SUMMARY: In an acute inhalation toxicity study, five young adult Hsd: Sprague Dawley SD rats/sex (Age: 9 weeks; Weight: 282-307 g males; 215-225 g females; Source: Harlan Sprague Dawley, Inc., Indianapolis, IN) were exposed by nose-only inhalation to V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid) at 2.11 mg/L for 4 hours. Body weights were obtained prior to dosing on day 0 and on days 7 and 14. All animals were observed for clinical signs of toxicity and mortality during the exposure and for 14 days post exposure. Gross necropsies were performed on all animals.

Inhalation LC_{50} Males = > 2.11 mg/L (observed); Inhalation LC_{50} Females = > 2.11 mg/L (observed)

V-53482 4 FL is classified as Toxicity Category IV based on the observed LC_{50} values in both sexes.

All animals survived the exposure. One female lost weight during the first week and one female lost weight during the second week. All other animals gained weight during the study. Clinical signs noted were congested breathing, few feces and dark material around the nose and/or mouth. The animals recovered from these symptoms by day 3. The gravimetric chamber concentration was 2.11mg/L. The mass median aerodynamic diameter was 5.9 µm with a geometric standard deviation of 2.5. No gross abnormalities were noted at necropsy.

This study is classified as Acceptable (870.1300) and satisfies the guideline requirement for an acute inhalation study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Exposure Concentration mg/L (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.11	0/5	0/5	0/10

Chamber Atmosphere		
Gravimetric conc.	MMAD	GSD
2.11 mg/L	5.9 µm [a]	2.5

[a] 34% of the particles were ≤ 4.0 µm

Chamber Environment[a]	
Chamber Volume	10 L
Airflow	25 LPM
Temperature	69 °F
Relative Humidity	77-82 %

[a] nose only

OBSERVATIONS: All animals survived the exposure. One female lost weight during the first week and one female lost weight during the second week. All other animals gained weight during the study. Clinical signs noted were congested breathing, few feces and dark material around the nose and/or mouth. The animals recovered from these symptoms by day 3.

GROSS NECROPSY: No gross abnormalities were noted at necropsy.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY EYE IRRITATION TESTING (870.2400 formerly §81-4)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: V-53482 4 FL; 41.5% flumioxazin

CITATION: Rodabaugh, D. (2002) primary eye irritation in rabbits with V-53482 4 FL. Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number 3548.31. May 15, 2002. MRID 45687105. Unpublished.

SPONSOR: Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596-8025

EXECUTIVE SUMMARY: In a primary eye irritation study, 0.1 mL of V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid) was placed into the conjunctival sac of the right eye of three male adult New Zealand White rabbits (Source: Myrtle's Rabbitry, Thompson Station, TN). All animals were observed for ocular irritation at 1, 24, 48 and 72 hours post-instillation.

V-53482 4 FL is classified as Toxicity Category III based on the irritation observed and resolution by 48 hours.

Iritis was noted in 2/3 eyes and conjunctivitis in 3/3 eyes at the one hour observation. By 48 hours, no positive results were noted.

This study is classified as Acceptable (870.2400) and satisfies the guideline requirement for a primary eye irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Observations	Number "positive"/number tested				
	Hours				Days
	1	24	48	72	7
Corneal Opacity	0/3	0/3	0/3	0/3	0/3
Iritis	2/3	0/3	0/3	0/3	0/3
Conjunctivae:					
Redness*	3/3	2/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3	0/3
Discharge*	0/3	0/3	0/3	0/3	0/3

*Score of 2 or more required to be considered "positive."

OBSERVATIONS: Iritis was noted in 2/3 eyes and conjunctivitis in 3/3 eyes at the one hour observation. By 48 hours, no positive results were noted.

DATA EVALUATION RECORD

STUDY TYPE: PRIMARY DERMAL IRRITATION TESTING (870.2500 formerly §81-5)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: V-53482 4 FL; 41.5% flumioxazin

CITATION: Rodabaugh, D. (2002) primary skin irritation in rabbits with V-53482 4 FL. Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number 3548.32. May 15, 2002. MRID 45687106. Unpublished.

SPONSOR: Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596-8025

EXECUTIVE SUMMARY: In a primary skin irritation study, three adult male New Zealand White rabbits (Source: Myrtle's Rabbitry, Thompson Station, TN) were dermally exposed to 0.5 mL of V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid) for 4 hours. The test substance was applied to a single 1 inch x 1 inch intact dose site on each animal. Animals were observed 1, 24, 48 and 72 hours after patch removal.

V-53482 4 FL is classified as Toxicity Category IV based on irritation observed and resolution by 72 hours.

Primary Dermal Irritation Index (PDII) = 1.00 Well defined erythema was noted at all test sites at the one hour scoring. All sites were free of dermal irritation by 72 hours.

This study is classified as Acceptable (870.2500) and satisfies the guideline requirement for a primary skin irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS: Primary Dermal Irritation Index (PDII) = 1.00

OBSERVATIONS: Well defined erythema was noted at all test sites at the one hour scoring. All sites were free of dermal irritation by 72 hours.

DATA EVALUATION RECORD

STUDY TYPE: DERMAL SENSITIZATION TESTING (870.2600 formerly §81-6)

Product Manager: 23 **Reviewer:** Eugenia McAndrew

TEST MATERIAL PURITY: V-53482 4 FL; 41.5% flumioxazin

CITATION: Rodabaugh, D. (2002) dermal sensitization in guinea pigs with V-53482 4 FL. Modified Buehler Design. Springborn Laboratories, Inc., Spencerville, Ohio. Laboratory Report Number 3548.33. May 15, 2002. MRID 45687106. Unpublished.

SPONSOR: Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596-8025

EXECUTIVE SUMMARY: In a dermal sensitization study conducted with V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid), 30 young adult male and female Hartley - derived albino guinea pigs (Age: males - 6 weeks; females - 8 weeks; Source: Hilltop Lab Animals, Inc., Scottdale, PA) were tested using a modified Buehler design. Preliminary testing was conducted with four animals to determine the correct concentrations for induction and challenge. In the main study, twenty test animals were induced with three applications (six hours/exposure, once per week for three weeks) of 0.3 mL of test substance at 100% concentration. On day 27, 0.3 mL of 100% concentration (highest non-irritating concentration) of the test substance was applied to the twenty test guinea pigs and to ten naive control guinea pigs for a six-hour challenge exposure. Reactions were scored 24 and 48 hours after each induction and after the challenge. A positive control study using α-hexylcinnamaldehyde (HCA) was conducted within six months of the main study to validate the test system.

V-53482 4 FL is classified as a non-sensitizer based on the results of this study.

No dermal irritation was observed at any of the test animal sites during the induction phase. Following the challenge, no dermal irritation was observed at any of the test animal sites or at the naive control animal sites. Based on these results, the test substance is not considered to be a contact sensitizer. The positive response observed in the HCA study validates the test system used in this study.

This study is classified as Acceptable (870.2600) and satisfies the guideline requirement for an dermal sensitization study in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

PROCEDURE: In a dermal sensitization study conducted with V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid), 30 young adult male and female Hartley - derived albino guinea pigs (Age: males - 6 weeks; females - 8 weeks; Source: Hilltop Lab Animals, Inc., Scottdale, PA) were tested using a modified Buehler design. Preliminary testing was conducted with four animals to determine the correct concentrations for induction and challenge. In the main study, twenty test animals were induced with three applications (six hours/exposure, once per week for three weeks) of 0.3 mL of test substance at 100% concentration. On day 27, 0.3 mL of 100% concentration (highest non-irritating concentration) of the test substance was applied to the twenty test guinea pigs and to ten naive control guinea pigs for a six-hour challenge exposure. Reactions were scored 24 and 48 hours after each induction and after the challenge. A positive control study using α-hexylcinnamaldehyde (HCA) was conducted within six months of the main study to validate the test system.

RESULTS: No dermal irritation was observed at any of the test animal sites during the induction phase. Following the challenge, no dermal irritation was observed at any of the test animal sites or at the naive control animal sites. Based on these results, the test substance is not considered to be a contact sensitizer. The positive response observed in the HCA study validates the test system used in this study.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D283614
2. **PC CODE:** 129034
3. **CURRENT DATE:** 12/SEPT/2002
4. **TEST MATERIAL:** V-53482 4 FL (41.5% flumioxazin; Lot No. VDL-631-03-2; white liquid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Springborn Laboratories, Inc. 3548.28/5-15-02	45687102	LD_{50} > 5000 mg/kg (males females combined)	IV	A
Acute dermal toxicity/rat Springborn Laboratories, Inc. 3548.29/5-15-02	45687103	LD_{50} > 5000 mg/kg (males females combined)	IV	A
Acute inhalation toxicity/rat Springborn Laboratories, Inc. 3548.30/5-15-02	45687104	LC_{50} > 2.11 mg/L (males females combined)	IV	A
Primary eye irritation/rabbit Springborn Laboratories, Inc. 3548.31/5-15-02	45687105	Iritis and conjunctivitis at one hour. No positive effects at 48 hours.	III	A
Primary dermal irritation/rabbit Springborn Laboratories, Inc. 3548.32/5-15-02	45687106	PDII = 1.00 Dermal irritation resolved by 72 hours.	IV	A
Dermal sensitization/guinea pig Springborn Laboratories, Inc. 3548.33/5-15-02	45687107	Non-sensitizer	–	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**